

Docket No. MCP 231

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Parikh, et al.

Serial No. : 09/745,243

Art Unit: 1616

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Examiner: Choi, Frank

For : TEXTURE MASKED PARTICLES CONTAINING AN ACTIVE
INGREDIENT

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19 October, 2005

Michele G. Mangini

Name of applicant, assignee, or Registered Representative

Michele G. Mangini
(Signature)19 October, 2005

(Date of Signature)

Assistant Commissioner For Patents
Washington, D.C. 20231

DECLARATION UNDER 37 CFR 1.132

Dear Sir:

I, David W. Wynn, hereby declare:

1. I am one of the joint inventors of the U.S. Patent Application Serial No. 09/745,243, entitled "TEXTURE MASKED PARTICLES CONTAINING AN ACTIVE INGREDIENT" identified above.

2. Since approximately January 1995, I have been employed by McNEIL-PPC, Inc. in the positions of Senior Research Associate, Research Scientist, , and now as Patent Liaison. Between about June, 1992 and January, 1995, I was in the employ of Johnson & Johnson - Merck Consumer Pharmaceuticals Company in the positions of Research Associate and Research Assistant. My technical experience includes, but is not

limited to, development of novel solid dosage form technology and evaluation of new process technology such as taste-masking/particle coating, with particular emphasis on fluid-bed and high shear granulation, Rotor/Wurster particle coating, solid dose blending, tablet compression, and tablet coating.

3. In 1992 I received a Bachelor of Science Degree in Chemistry from Dickinson College, and in 1999 I received a Masters of Science Degree in Quality Assurance/Regulatory Affairs Pharmaceuticals from Temple University.

4. I am aware that the United States patent and Trademark Office has rejected the claims of the above-referenced application based upon JP 2-53271 in view of United States Patent No. 6,139,865 to Friend, et al. ("Friend"); CA 2068366, and United States Patent No. 5,958,458 to Norling, et al. ("Norling").

5. **Preparation of Coating Solutions**

I prepared a film coating solution by dissolving hydroxypropylmethylcellulose (5 centipoise grade)("HPMC") and polyethylene glycol 8000 ("PEG"), and by dispersing an amount of talc, in an ethanol and purified water mixture under ambient conditions, so that the finished solution contained 7.2% by weight of the coating materials. The weight ratio of HPMC:PEG was 60:40. The ratio of ethanol to purified water was 71.2 to 28.8 percent in accordance with Example 3 of JP 2-53271. I then allowed the solution to deaerate for a minimum of 2 hours prior to use.

I repeated these steps to prepare three additional batches of film coating solutions, but I varied the ratio of HPMC: PEG in each respective batch as indicated in Table A below. I kept the level of talc consistent in each of the batches with the amount used in Example 3 of JP 2-53271. I used HPMC: PEG in an amount of 13:1 in the coating solution of Batch 4, which is in accordance with the coating solution of Example 3 in JP 2-53271. The relative amounts of the coating materials are, based upon the weight percent of the final coating:

Table A – Coating Solutions**Batch 1 60/40 [1.5:1] HPMC/PEG ratio**

Polyethylene Glycol 8000.....[40]... 38.9 %
Hydroxypropylmethylcellulose 5 cps..... [60]... 58.3%
Talc.....2.8%

Batch 2 80/20 [4:1] HPMC/PEG ratio

Polyethylene Glycol 8000.....[20]... 19.4 %
Hydroxypropylmethylcellulose 5 cps..... [80]... 77.8 %
Talc.....2.8%

Batch 3 90/10 [9:1] HPMC/PEG ratio

Polyethylene Glycol 8000.....[10]... 9.7 %
Hydroxypropylmethylcellulose 5 cps..... [90]..... 87.5%
Talc.....2.8%

Batch 4 93/7 [13:1] HPMC/PEG ratio

Polyethylene Glycol 8000.....[7]... 6.9 %
Hydroxypropylmethylcellulose 5 cps..... [93]..... 90.3. %
Talc.....2.8%

6. Preparation of Coated APAP Granules

I then obtained acetaminophen granules that had been previously coated with a tastemasking solution in a commercial scale Glatt Rotor 200 GPCG fluid bed unit. The tastemasking solution contained a combination of cellulose acetate and povidone, in a ratio of 85 and 15 respectively, with a weight gain of 11.0% polymer. The level of acetaminophen in the taste-masked granules was 89.0%.

For each batch outlined in Table A, I coated 500.0g of taste-masked acetaminophen granules with one of the four texture-masking coating solutions described in Table A at a spray rate of about 10-16 g/min in a Glatt GPCG-1/3 fluid bed unit with a rotor insert under product temperature conditions of about 28-35°C and an atomization air pressure of 2.5 - 3.0 bar until a 10.0% weight gain was achieved. That

is, the resulting texture-masked acetaminophen contained, based upon the total dry weight of the texture-masked acetaminophen, about 10% of the texture-masking coating.

I then prepared 12 samples of Batch 2 (80:20 blend) and 12 samples of Batch 4 (93:7 blend), by measuring 225 mg of each respective coated acetaminophen product and placing each measured product into an individual dosing cup.

7. Texture Masking Comparative Testing

I contacted 12 persons to participate in a blind taste test in which the samples of Batch 2 [80:20 HPMC:PEG ratio] were compared with the samples of Batch 4 [93:7 HPMC:PEG] with respect to grittiness. I asked each person to chew each sample then evaluate the texture as a function of grit when ingested.

The results were as follows:

| <u>Sample</u> | <u>Number of Persons</u> <u>Preferring Texture of</u> <u>Sample</u> |
|--------------------------------|--|
| Batch 2 [80:20 HPMC:PEG ratio] | 11/12 |
| Batch 4 [93:7 HPMC:PEG ratio] | 1/12 |

This Example showed that 11 out of 12 persons determined that the samples containing particles coated with an 80:20 HPMC:PEG coating were less gritty (e.g., had better texture) than the samples containing particles coated with a 93:7 HPMC:PEG coating. This Example illustrates that the texture masking coating 80:20 HPMC:PEG was unexpectedly superior relative to prior art coated dosage forms.

8. I, David W. Wynn, further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further declare that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both,

under 35 USC §1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issuing thereon.

By: David W. Wynn
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Date: 10/6/05